**INTENDED USE**

The FYL Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Fentanyl in human urine specimens at the cut-off concentrations listed below.

**PARAMETER** | **CUT-OFF (ng/ml)**  
--- | ---  
Fentanyl (FYL) | 200  

**PRINCIPLE**

Fentanyl is a synthetic opioid related to the phenylopiperidines. Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly crosses the blood-brain barrier. This is reflected in the half-lives for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl and 160 minutes for morphine. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

The FYL Rapid Test Strip (Urine) detects Fentanyl through visual interpretation of color development on the strip. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action and interacts with the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent the antibody-colored particle conjugate from binding to the drug conjugates, forming a colored band at the test region of the membrane.

**SPECIMEN COLLECTION AND STORAGE**

**MATERIALS**

- Test strips (individually pouched or in canisters)  
- Positive and negative controls  
- Centrifuge

**PROCEDURE**

1. Remove the test strip from the canister, and use it as soon as possible. For best results, the test strip should be performed within one hour. Canisters should be closed tightly after removing strips.
2. Bring the specimen to room temperature prior to testing. Frozen specimens must be completely thawed before testing.
3. After the test strip has finished running, remove the strip from the specimen and place it on an absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

**INTERPRETATION OF RESULTS**

- **POSITIVE:** Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).
- **NEGATIVE:** Two colored bands appear on the membrane. One band appears in the control region (C), and another band appears in the test region (T).
- **INVALID:** Control band fails to appear. Results from any test which has not produced a control band (C) and another band appears in the test region (T).

**VALIDATION AND QUALITY CONTROL**

- **QUALITY CONTROL**
  - Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
  - External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS OF THE TEST**

1. The FYL Rapid Test Strip (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Fentanyl in human urine specimens.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Fentanyl only, and does not indicate or measure intoxication.

**PERFORMANCE CHARACTERISTICS**

**ACCURACY**

The accuracy of the FYL Rapid Test Strip (Urine) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

**REPRODUCIBILITY**

The reproducibility of the FYL Rapid Test Strip (Urine) was verified by blind tests performed at four different locations. Samples with Fentanyl concentrations at 50% of the cut-off were all determined to be negative, while samples with Fentanyl concentrations at 200% of the cut-off were all determined to be positive.

**SPECIFICITY**

Test precision was determined by blind tests with control solutions. Controls with Fentanyl concentrations at 50% of the cut-off yielded negative results, and controls with Fentanyl concentrations at 150% of the cut-off yielded positive results.

**Fentanyl related compounds**

- Fentanyl 100 ng/ml
- Norfentanyl 70,000 ng/ml

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- **INVALID:** Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue the use immediately and contact your local distributor.

**QUALITY CONTROL**

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